Dear Secretary Azar and Administrator Verma:

On behalf of all participating members, stakeholders, and constituents of the HL7® Da Vinci Project, and in close collaboration with HL7®, we appreciate the opportunity to provide comments to the Department of Health and Human Services (HHS) regarding the Proposed Rule published in the Federal Register on December 18, 2020 "establishing standards for the interoperability of health information and facilitating access by health care providers to information about prior authorizations."

The HL7 Da Vinci Project plays a pivotal enabling role in advancing the data exchange infrastructure essential to making the health care system work better for all constituents.

As an HL7 FHIR® Accelerator, the Da Vinci Project's primary mission is to improve the health care delivery system by accelerating interoperability while reducing administrative burden. This mission aligns with the Department of Health and Human Services (HHS) goal "to drive interoperability, improve care coordination, reduce burden on providers and payers, and empower patients."

HL7® FHIR Accelerators anchor to a shared vision to share best practices, and the Da Vinci Project prides itself on achieving this goal in an industry-first manner.

Growing sponsorship and engagement from our Da Vinci Project membership and the broader standards community confirms strong commitment to and support of the Da Vinci Project Accelerator program.

We look forward to the continued collaboration across private and public sectors to improve health outcomes, increase transparency, and reduce the administrative burden.
Sincerely,

Sagran S. Moodley
Chair, Da Vinci Steering Committee
HL7 Da Vinci Project

CC: Da Vinci PMO
Da Vinci Members

For a complete listing of current committee members:
https://confluence.hl7.org/display/DVP/Da+Vinci+Steering+Committee+Members

Enclosure: HL7® Da Vinci Project NPRM Feedback - Reducing Provider and Patient Burden

To Learn More about the project:

To learn more about Da Vinci and access project resources:
Da Vinci Welcome - https://confluence.hl7.org/display/DVP/Da+Vinci+Welcome
Da Vinci Implementer Support - https://confluence.hl7.org/display/DVP/Da+Vinci+Implementer+Support
Da Vinci Main Home Page - https://confluence.hl7.org/display/DVP/Da+Vinci
HL7® Da Vinci Project NPRM Feedback  
Reducing Provider and Patient Burden

January 4, 2021

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9123-P  
P.O. Box 8016  
Baltimore, MD 21244-8016


Dear CMS Staff

Thank you for the opportunity to comment on the referenced proposed rule. The HL7® Da Vinci Project, its membership, and growing community of FHIR adopters appreciate the recognition and value placed on their work in the proposed rule to:

1. Enhance the exchange of patient specific information between patients, providers, and payers,  
2. Make the information required for a particular service accessible, and  
3. Automate the process of submitting and obtaining prior authorization (PA) for a specific patient. This will be done through the required use of Da Vinci's Implementation Guides:
   a. Coverage Requirements Discovery (CRD)  
   b. Documentation Templates and Rules (DTR)  
   c. Prior Authorization Support (PAS)

Implementation Guides (IGs), leveraging HL7 FHIR®, enable the industry to make meaningful progress to reduce unnecessary waste and burden for all participants in health care, while ensuring the core functions of medical necessity, cost and safety remain in place. The momentum we see across our provider, payer, and vendor communities on unlocking prior authorization is growing, and we look forward to the increased attention and focus that the final regulation will provide.

In addition, the inclusion of previously named resources from Da Vinci and CARIN IGs needed to meet the requirements of Patient Access API regulation for the July 1, 2021, expands the participants to include providers and fuels the industry’s continued shift to value based care. These specific named IGs will:

1. Increase speed of adoption by creating standard, reusable, and flexible APIs  
2. Reduce complexity and maintenance costs necessary to support continuity of care and sharing of critical patient information at the point of care  
3. Ensure better patient care by increasing information parity across all stakeholders  
4. Reduce existing gaps in patient specific information  
5. Increase automation of transactions by providing structured and coded data

The Da Vinci Project Management Office (PMO), with feedback from our membership, would like to make the following comments and suggestions regarding specific proposals in the NPRM:
It is important to Include Medicare Advantage (MA) plans and Medicare fee-for-service (FFS) plans (pg. 9)

The proposed rule does not include MA plans. We strongly encourage inclusion of these in a future rule and suggest that Medicare FFS plans adopt the same standards. A critical mass of covered lives is necessary to gain meaningful end user adoption. In order for provider and payer teams to make the business process shifts to these operational efficiencies and thus impact patient decision making, providers must be able to see this fuller picture of a patient’s options and cost early enough in episodes of care and across a significant portion of the patient panels. From the technology and workflow perspectives, the Da Vinci community agrees that increasing the provider community’s access to this critical information via APIs is key. To gain widespread end user adoption of these use cases, it will be critical to ensure that patient specific data is accessible and easily available via APIs. If CMS does not require MA plans to support the same technology standards as proposed in this NPRM, implementations supporting MA plans may have different API requirements than plans impacted by the proposed rule. This will create significant challenges for both payers and application vendors, and ultimately impact patient access.

Definition of personal representative (pg. 10)

The Da Vinci Project community requires greater clarity on the definition of personal representative (pg. 10). It is critical that CMS adopt consistent, specific terminology for the roles and actors leveraging the APIs called out in regulation. To ensure security, patient privacy and free data for patients’ use, the term “personal representative” should include the superset of designees defined in the previous final rule for Patient Access API.

Requirement for making claims data available for all APIs (pg. 19 and regulation language)

The requirement in the regulation language portion of the NPRM specifies that claims and encounter information should be made available within or no later than “one (1) business day after receipt.” The preamble language states that “We required that data must be made available no later than one (1) business day after a claim is adjudicated or encounter data are received”. In the CMS Interoperability final rule, the requirement is “one (1) business day after processing” or “one (1) business day after adjudication”. We propose that CMS adopts “one (1) business day after adjudication” in all situations for claims information.

Definition of clinical data and standard for exchange (pg. 22-23)

CMS requested feedback regarding the use of US Core and PDex in the Patient Access API. The NPRM states “we propose that payers would be allowed to conform with either the US Core IG or the PDex IG to facilitate making the required USCDI data available via the Patient Access API.” It is important to note that the PDex IG is inclusive of US Core profiles and includes additional profiles to support payer processes. We recommend that CMS require the use of the PDex IG and remove the optionality to use either US Core or PDex. We also recommend providing additional clarification that PDex applies to payer APIs and not all APIs that vendors would implement for other purposes. In non-payer workflows, the additional profiles beyond US Core in the PDex IG may not be necessary.

We strongly agree that the current US Core profiles (STU3.1.1) do not contain all the profiles needed by payers. For example, US Core does not include a FHIR Coverage profile to support standard exchange of insurance information. Additionally, the US Core Implantable Device profile does not support other non-implantable devices such as wheelchairs. The Da Vinci Project submitted feedback to ONC regarding the addition of these and other data classes and elements in the next update to USCDI.

Also, we recommend clarification of guidance language to emphasize USCDI instead of “clinical data including lab results,” which may cause confusion.

Floor and adoption of new version (pg. 21)

The Da Vinci Project endorses the concept of a “floor” for standards with identification of initial IG versions that support the functionality required by the rule and compliance dates for these IGs. We recognize that IGs undergo a maturation process through implementation and balloting. We recommend the following process for adoption of updated published versions of each IG named in the proposed regulation:

1. Where these updated versions are required to meet the final rule requirements, the updates shall be required (this is the “floor”) and the timelines in the final rule should apply.
2. Where updated versions of IGs provide for enhanced optional functionality, entities subject to the final rule that wish to implement the enhanced functionality must do so in a manner compliant with the updated IG version. However, the entity must continue to support all functionality in the “floor” version of the standard.
The only way to move the “floor” requirement to a more recent version of the IG (other than to meet regulation requirements) is to update the respective regulation.

Coverage of Prior Authorization for drugs (pg. 27)

The Da Vinci Project community fully appreciates and understands the maturity and widespread automation of retail pharmacy for dispensed medications and supporting services. That said, we recognize the stalled challenge of achieving full automation due to the lack of adoption and maturity for medications covered under medical benefit or dispensed in facilities covered by Part B coverage. We strongly suggest that CMS not leave a PA gap for these medications. Clear guidance must be given that medications and services either performed in a facility or covered under medical benefit have clear requirements to automate. Specific language to ensure coverage of these items should be included.

Attestation (pg. 30-34)

We agree with the scope of questions that should be part of any application attestation. It will be hard to have an ‘all or nothing’ approach to the attestation questions given that some will have options to select (e.g., disposition of data on leaving).

However, the attestation process as stated in the NPRM is confusing and counter to industry standards. We propose that the process should be defined as requiring an attestation at the time an application is registered with a trusted third party or with the impacted payer. This process must happen before an application may be authorized by a patient to access their information via the Patient Access API. The developer should either attest at the time of registration or be given 5 business days to respond to the request for attestation, after which the application should be marked as having no response from the developer. When a patient attempts to authorize an application, the existing attestation (or lack of) should be presented to the patient. If the patient fails to acknowledge the attestation, then the application should not be authorized to access the patient’s information. This acknowledgement or failure to acknowledge should be maintained as information associated with the patient and the application available for reporting (without the patient’s demographics).

Change enrollees to parties (pg. 37)

While changing enrollees to parties may improve readability for certain sections of the rule, the preamble also defines “patient” very broadly. We suggest that CMS not use parties to define any role that is covered by the term patient as defined in the NPRM preamble.

P Dex Plan Net requirement (pg. 38-39)

The Da Vinci Project supports the requirement to use the P Dex Plan Net IG as the standard for covered payers to provide API access to their provider directory. In addition, we agree that all impacted plans should support the same standard to reduce the variability and make it more convenient for patients to access a plan’s list of covered providers.

Opt-out, not Opt-in (pg. 49-51, 64-66, basic response)

With respect to Opt-in versus Opt-out, payers (directly and through their with Health Information Exchange Organizations) already have extensive challenges and poor experiences with patient Opt-in. Therefore, we strongly favor an annual Opt-out process as an effective way to have adequate and broad engagement, and to protect patient rights. Patients would have the right to Opt-out at any time; when changing plans, and when an out-of-network provider seeks their data. From an adoption perspective, it is critical that the final rule support the following industry best practice of Opt-out functionality:

Multiple options need to exist for outreach to patients, such as text, email, phone, and the patient should be encouraged to select at least two options as a means to help ensure the patient has several channels to receive notification of the annual request and any out-of-network provider requests.

Provider access API (pg. 53-55) and bulk data (pg. 57-59)

The Da Vinci Project strongly endorses CMS’s intent to require that impacted payers support the creation of a Provider API as defined by the NPRM. However, there does not appear to be a rationale for supplying both the EOB, as defined by the CARIN Blue Button IG, and the clinical data support, as defined by the P Dex IG. Since there is no intent to exchange cost information associated with an EOB, the support in the P Dex IG for USCDI information covers all the relevant items available in the EOB and therefore the two appear to be duplicative in relation to the exchange of claims and encounter information. We suggest that CMS consider requiring only support for USCDI information as defined by the P Dex IG and require that any USCDI information available from a claim or encounter must be available via the Provider API as defined in the P Dex IG. This would then require
only the use of the PDex IG, the PDex Formulary IG, and (depending upon the decision made by CMS) either the PDex IG (as written) or the PCDe IG to support prior authorization information.

Regarding support for bulk data, it is unclear if CMS intends to have each IG support the bulk data standard or whether the desire is to have a bulk data standard available to support the exchange of all information defined by the Provider API in a single request. In either case, there will be a need to modify/enhance the cited IGs to support the use of bulk data. To adequately support the use of bulk data with the named IG, there needs to be an additional query process for multiple patients (may include the use of a validated “member roster”) and examples to support implementers. This will help avoid the creation of multiple different solutions.

We note that the PDex IG must be extended to support prior-authorization data as defined in the NPRM. This is work that can addressed in 2021 and made available as an update to the PDex IG.

Attribution (pg. 62-64)

Regarding patient attribution, we recommend the identification of the Da Vinci Risk Based Contracts Member Attribution (ATR) List IG, which is currently in the publication process. While this IG is focused on attribution lists for risk-based contracts, it will equally serve as the exchange standard for fee-for-service (FFS) products. The IG needs to have workflow and specific content examples for FFS, including the CMS Data at the Point of Care (DPC) pilot. This IG includes the use of bulk data and is an example of the importance of specifying bulk data queries and responses within an IG and not broadly with a single bulk data IG. We suggest that the term “provider” should be clarified to include either an individual provider or a provider organization.

Expansion of X12 278 and alternative approaches (pg. 85)

The Da Vinci Project proposes that CMS strives to reduce the barrier to exchanging the FHIR bundle specified by the PAS IG directly between the provider and the payor without requiring translation into and out of the X12 278 standard. Since the current HIPAA regulation requires the use of the X12 278 for prior authorization, CMS will either need to work with lawmakers to modify the statute (and issue a new regulation) or lower the requirements for an exception, as allowed by current HIPAA transaction regulation. In the latter case, CMS should allow trading partners to request the exception by completing a standard form and substantially reduce the reporting requirements and cost associated with each exception.

For clarity, we are not proposing to discontinue support of the X12 278.

Support for DRLS (pg. 86)

The Da Vinci Project is supportive of CMS’s effort to streamline the prior authorization process and reduce the burden for providers, patients, and payers. The initial step of providing a repository of prior authorization requirements, or DRLS as noted in the NPRM, is a necessary and obvious first step. CRD should be required for all prior authorization items and services by 1/1/2023.

Our key concern is requiring that all services and items requiring DTR rules for prior authorization, except for outpatient medications, must be supported by 1/1/2023. We suggest that CMS consider the initial set of items and services should be the same as the initial 500 items and services defined in the Cost Transparency Final Rule, where the item or services is the subject of prior authorization for the covered plan. Final rule compliance date for all items and services should be 1/1/2024.

Encouraging adoption of PA in EHR and incentivize use of DRLS (pg. 88) (pg. 93-94)

The Da Vinci Project suggests that CMS could encourage the adoption of the proposed prior authorization standards and the use of DRLS by providing incentives to providers to utilize DRLS and automated prior authorization as proposed in this NPRM. Incenting providers to utilize the DRLS and PA API will ensure that EHR vendors support these IGs. CMS could do this by making use of DRLS and PAS a target criterion for value-based payments to providers. An alternative is to include a requirement for certified EHR’s to support the three relevant IGs as part of a future certification criteria. The appropriate timing for that criteria would most likely be 1/1/23 to coincide with the proposed timeline for payer support for DRLS and PAS.
Support for payer implementation of a PA API (pg. 90-93)

The process defined by the NPRM for payer support for a PA API is:

“The API would send the request through an intermediary (such as a clearinghouse) that would convert it to a HIPAA compliant X12 278 request transaction for submission to the payer. It is also possible that the payer converts the request to a HIPAA compliant X12 278 transaction, and thus the payer acts as the intermediary. The payer would receive and process the request and include necessary information to send the response back to the provider through its intermediary, where the response would be transformed into a HIPAA compliant 278 response transaction.”

We suggest that the first sentence should read as follows:

“The payer is responsible for establishing the ability to convert the PAS IG specified FHIR bundle to a HIPAA compliant X12 278 request by working with an intermediary (such as a clearinghouse).”

EHR support for DRLS and PAS (pg. 93-94)

The Da Vinci Project strongly suggests that CMS should work with ONC to ensure that EHRs are ready to support CRD, DTR and PAS on the same timeline as the payers.

Payer-to-Payer Data Exchange ’PCDE’ (pg. 148-154)

The Da Vinci Project strongly supports CMS’s intent to require that the Payer-to-Payer exchange utilize a standards-based payer-Payer API as defined by the NPRM. However, there does not appear to be a rationale for supplying both the EOB as defined by the CARIN Blue Button IG and the clinical data support as defined by PDex IG. Since there is no intent to exchange cost information associated with an EOB, the support in PDex IG for USCDI information covers all the relevant items available in the EOB and therefore the two appear to be duplicative in relation to the exchange of claims and encounter information. We suggest that CMS consider requiring only support for USCDI information as defined by the PDex IG and require that any USCDI information available from a claim or encounter must be available via the Provider API as defined in the PDex IG. This would then require only the use of the PDex IG, the PDex Formulary IG, and (depending upon the decision made by CMS) either the PDex IG (as the proposed regulation language is written) or the PCDE IG to support prior authorization information.

Concerning support for bulk data, it is unclear if the intent of the proposed rule is to have each IG support the bulk data standard or the desire is to have a bulk data standard available to support the exchange of all information defined by the Payer-Payer API in a single request. In either case, there will be a need to modify/enhance the cited IGs to support the use of bulk data. To adequately support the use of bulk data with the named IGs, there needs to be additional query processes for multiple patients (may include the use of a validated “member roster”) and examples to support implementers and avoid the creation of multiple different solutions.

Bulk Data for PCDE (if supported in the final rule) will require significant enhancements to the current IG. The current IG is focused on providing information on active treatment for a single patient and uses the $memberMatch to establish that both payers are referring to the same patient before exchanging a specific FHIR document with information regarding current active treatment (not just information related to prior authorization). There is an assumption that it will take time to assemble the necessary information (e.g., it may require the assembly and attachment of unstructured documentation). Therefore, the PCDE IG does not provide the ability to easily exchange PA information for multiple patients or meet the 1 (one) business day requirements. We recommend that PCDE be included in the final rule but focused on the original intent of one patient at a time and only through payer-to-payer exchanges during enrollment. The timeline for the exchange of information via PCDE should be 10 days initially and shortened to 3-5 day as the PA solutions are deployed.

The Da Vinci Project recommends that the Payer-Payer data exchange API should include the requirement to exchange information that is not in the API format (that is required to be exchanged “in form and format in which it was received”) by using the FHIR documentReference resource. By doing this, the payer-to-payer exchange will utilize only the Payer-Payer API and not require other exchange methods for information received and exchanged in the form and format in which it was received.

We also recommend that the Payer-Payer exchange defined in the CMS Interoperability Final Rule not be required or, at a minimum, not enforced until this rule takes effect. This will minimize the exchange of information that does not conform to the FHIR APIs defined in this proposed rule.
Payer-Payer API sharing data at enrollment (pg. 154)

The Da Vinci Project agrees with the concept of supporting peer-to-peer exchange via an API at enrollment and between payors with concurrent coverage for a patient on a regular interval. Similarly, we have the same comment for the payer-to-payer exchange above as it applies to the peer-to-peer exchange of data at enrollment. In addition, using bulk data for exchange to support coordination across concurrent payers will require some additional work with the P Dex and PCDE IGs. In the case of exchange between concurrent payers, it will be necessary to ensure that the information exchanged is only new information that has been created by the payer in the interval since the last exchange.

One consideration for CMS is that the Payer Coverage Decision Exchange (PCDE) IG was designed to take advantage of the HIPAA right for payers to exchange information for coordination of care without the need for patient authorization. CMS should consider if coordination between current payers requires patient consent and if it does, they may wish to restrict the coordination activity to PCDE alone.

Adopt IGs as part of the ONC specification for APIs (pg. 15) (pg. 184-186)

With respect to the coordination of the CMS rules with those from ONC, we recommend a method or process to incorporate the IG in the CMS rules into the ONC certification criteria and process. This would apply to health IT vendors who provide certified health IT products that need to support the IGs named in the CMS rules.

RFI – Methods for Enabling Patients and Providers to Control Sharing of Health Information (pg. 188-193)

In response to the RFI related to enabling patients and providers to control sharing of health information, the Da Vinci Project would like to comment as follows:

1. We understand the desire to allow individuals to determine how their information is used in the provision and support of their health care needs.
2. However, health care information is not easily separable into specific elements that do or do not impact specific clinical decisions (e.g., diagnosis and treatment), payment and operations.
3. Rather than regulate the ability to separate information into specific elements that may or may not be shared, we suggest that CMS consider for future regulations the requirement to implement a purpose of use standard for all covered entities (purpose of use value set should be limited to <15 values to enable unambiguous evaluation).
4. While this standard may not change federal and state regulations regarding additionally protected data (e.g., sensitive data), it should apply broadly to information required for Treatment, Payment and Operations (TPO) and replace any current or future considerations of minimum necessary (which are virtually impossible to establish given the complexity of many TPO information requirements).
5. By replacing minimum necessary with purpose of use, covered entities can ensure that information required to make TPO decisions is available to all covered entities that have a TPO relationship with the patient. Covered entities requesting access to PHI should be required to declare the purpose(s) for which they intend to use the information and regulations should hold them accountable for using it only for that/those purpose(s). The holder of the information should be able to automatically evaluate the request and based on the requester, requester’s relationship with the patient and the declared purpose of use, grant or deny access to specific requested uses of the information.
6. Additional work is needed to fully define the issues related to “purpose of use,” including the downstream issues related to payer-to-payer exchange.

RFI -- Reducing Burden and Improving Electronic Information Exchange of Prior Authorization (pg. 200-207)

In response to the NPRM RFI concerning Reducing Burden and Improving Electronic Information Exchange of Prior Authorization, the Da Vinci Project would like to comment as follows:

1. There is a need to support FHIR resources as the payload to ensure compliance with DTR and PAS (as part of burden reduction) and other FHIR IGs being implemented by payers.
2. We encourage the use of RESTful transactions to exchange clinical and administrative information.
3. If CMS plans to require the X12 275 as part of an Attachments rule, at a minimum, allow binary encoded FHIR Bundle in the BSD or Binary Segment in addition to or in place of a C-CDA (or CDA with US Realm Header)

Other Significant Issues:

1. The regulation language does not name the PCDE IG in any section other than 170.215(c) and 170.299(f)
2. CARIN Blue Button does not have profiles that allow for the exchange of an EOB without cost information.
3. Clarify if it is the intent of CMS with respect to CARIN BB to include adjudication information other than “cost” (e.g., CARCs and RARCs or verbiage to the patient) in the exchange if it is part of the final rule.

4. We support the ONC FAST recommendation to create a National Healthcare Directory with federated access to support the discovery of FHIR endpoints and their associated metadata (such as trust frameworks).

The Da Vinci community fully appreciates the hard work and deep understanding by the policy team represented in the NPRM.

We applaud the significant leadership that CMS is providing to the industry in its ongoing commitment to the Da Vinci Project and other standards development initiatives to reduce burden on providers and payers. We look forward to continued collaboration and progress in the months ahead and offer our comments in the spirit of moving the industry forward in a productive way.

Sincerely,

Jocelyn Keegan
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Viet Nguyen, MD
Technical Director, HL7 Da Vinci Project
Founder, Stratametrics

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CC: Da Vinci Operating Committee
Da Vinci Steering Committee

For a complete listing of current committee members:
https://confluence.hl7.org/display/DVP/DaVinci+Steering+Committee+Members
https://confluence.hl7.org/display/DVP/DaVinci+Operating+Committee+Members

To Learn More about the project:

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